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10/581,695	07/11/2006	Kazuhito Tanimoto	F-9067	1820
28107	7590	04/06/2009	EXAMINER	
JORDAN AND HAMBURG LLP			WRIGHT, PATRICIA KATHRYN	
122 EAST 42ND STREET			ART UNIT	PAPER NUMBER
SUITE 4000			1797	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,695	<b>Applicant(s)</b> TANIMOTO ET AL.
	<b>Examiner</b> P. Kathryn Wright	<b>Art Unit</b> 1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 March 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 and 12-16 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-10, 12-16 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 06 March 2009 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 06, 2009 has been entered.

### ***Status of the Claims***

2. This action is in response to papers filed March 06, 2009 in which claims 1, 3, 9-10 and 14-15 were amended and claim 16 was added. The amendments have been thoroughly reviewed and entered. Any objection/ rejection not repeated herein have been withdrawn by the Examiner. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 1-10 and 12-16 are under prosecution.

### ***Drawings***

3. The drawings are objected to because the replacement sheet filed March 06, 2009 does not contain a Figure number (i.e., Fig. 4).

4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-8 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Edelmann et al., (US Patent No. 4,814,144), hereinafter "Edelmann".

A reaction disk for an automatic analyzer, comprising:

a reaction disk body 12 which is rotatable about a centrally disposed rotational axis 50 running perpendicular to a horizontally disposed disk expande; and at least one separation cell 22 and at least one determination cell 16 is respectively arranged along a periphery of the reaction disk body located radially outward of the rotational axis,

the at least one separation cell and the at least one determination cell is provided as discrete cell units which are independently separate from one another in the same reaction disk at least a radially outward internal wall of each of the at least one separation cell and the at least one determination cell being maintained in a substantially parallel orientation with respect to the rotational axis even during rotation thereof of the reaction disk body.

The at least one separation cell includes a structural configuration (lid at element 22) for preventing a suspension from flowing out during centrifugal separation. The supernatant separated by the centrifugal separation from the suspension contained in the separation cell is dispensable to the determination cell to allow analysis of a target substance in the supernatant (see Figs. 2 and 4). Note that the supernatant is transferred from the separation cell to the determination with a pipette 36 (see entire document, in particular, col. 17, line 14 et seq.)

Regarding claim 2, Edelmann teaches a single motor being selectable so as to rotate at a first speed for rotating the separation cell for separation of the suspension into supernatant and insoluble matter and at a second speed for rotatably positioning the determination cell 9 for analysis (see col. 18, line 5 et seq.) Note the dispensing probe is not a positively recited element of the reaction disk and therefore does not serve to distinguish over the prior art.

With respect to claim 3, the separation cell in disk is provided with a lid at an upper portion of the separation cell above the insoluble matter collection zone to partially cover the separation cell (see for example col. 12, line 28 et seq.)

Regarding claims 4 and 5, Edelmann teaches dilution cells 72, 74, 76 that are kept in upright position during rotation. The dilution cell is arranged to be dispensed into the separation cell 22 via dilution 34 penetrating the stopper 62 to dilute the supernatant in the separation cell. The diluted sample is then aspirated by dispenser 26 and dispensed into the determination cell. With respect to claim 6, please note that the material worked on (i.e., the suspension is blood, insoluble matter is blood cell or the supernatant is plasma) is of no significance in determining patentability of the apparatus claim. The inclusion of material worked upon by a structure being claimed does not impart patentability to the claims. See MPEP 2114. Nevertheless, Edelmann teaches the supernatant is serum or plasma.

As to claim 15, the reaction disk body 12 of Edelmann is rotated during centrifugation and interior vertical side walls of each of the separation cell and the determination cell are arranged substantially parallel to the rotational axis defined by element 50 (i.e., vertical walls, see Fig. 2).

7. Claims 9-10, 12 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (US Patent No. 6,346,421), hereinafter "Anderson".

As to claims 9 and 16, Anderson teaches a cell disposed in a disk body. The disk body presenting a horizontally disposed disk expanse and being rotatable about a centrally disposed and vertically oriented rotational axis, see fig. 3F for example. The cell being disposed radially outward of the rotational axis and has an interior configuration including a lower part thereof defining an insoluble matter collection zone (bottom of chamber 38) and an upper part thereof defining a supernatant separation

zone, a horizontal cross sectional area of the supernatant separation zone is greater than a corresponding cross sectional area of the insoluble matter collection zone 44 thereby creating a step between the supernatant separation zone and the insoluble matter collection zone;

In some embodiments, a lid 160, 162 is disposed at an upper part of the cell in Anderson (see Figs. 9A-F). The lid being disposed to only partially cover the cell so as to leave an opening through which the supernatant is withdrawable from above while preventing the suspension in the cell from flowing out during centrifugal separation.

Regarding claim 10, Anderson teaches the shelf present at the boundary of the insoluble matter collection zone and the supernatant separation zone define a shelf (horizontal portion under in Fig. 3F) which extends horizontally from a radially inward side surface of the insoluble matter collection zone 22 towards the rotational center and which continues radially inward to corresponding radially inward side surface of the supernatant separation zone 18, other respective radially inward side surfaces of the insoluble matter collection zone and the supernatant separation zone, which are opposite to the radially inward side surface and the corresponding side surface, collectively forming a straight face in the cell, see Fig. 3E and 3F.

Regarding claim 12, the material worked on (i.e., the suspension is blood, insoluble matter is blood cell or the supernatant is plasma) is of no significance in determining patentability of the apparatus claim. The inclusion of material worked upon by a structure being claimed does not impart patentability to the claims. See MPEP 2114.

***Response to Arguments***

8. Applicant's arguments with respect to claims 1-10 and 12-16 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. Kathryn Wright/  
Examiner, Art Unit 1797